

Claims 22, and 36-39 are canceled making the rejection moot for these claims.

The protein of claim 1 shows significant similarity to E25AMM which has two biologically significant qualities that support utility: the protein is a membrane associated protein, and the protein is expressed in mature osteoblasts (for support, see the specification, page 2 line 10 et seq). These biological properties mean that the protein of claim 1 could be used as a membrane density marker, for example to assess/quantify membrane ruffling, or may be used as a tissue-specific marker (used to raise specific antibodies) to identify mature osteoblasts, which progenitor cells are of great significance (and economic importance) in a number of well-established areas of therapeutic investigation including osteogenesis and hematopoietic research.<sup>1</sup> Both such utilities are well established utilities, thus are not subject to the "specific utility" analysis of the recent guidelines. The fact that the protein's ligand is not known in no way decreases the protein's usefulness in identifying mature osteoblasts. Thus the applicants respectfully request that the rejection be withdrawn.

New claim 41 has been added which is directed solely to a method for using a protein of claim 1 for identifying mature osteoblasts in a mixed tissue sample. Applicants believe that this claim is sufficiently narrow and specific as to be allowable under the new guidelines, and ask for the examiner's consideration of this claim.

**Claim Rejections Under 35 U.S.C. § 112, first paragraph**

Claims 1, 2, 12, 21, 22 and 36-39 have been rejected under 35 U.S.C. § 112 as a corollary to the rejections under 35 U.S.C. § 101.

Claims 22, and 36-39 are canceled making the rejection moot for these claims.

On page 6 of the office action the examiner objects to "biologically active fragment" language. This has been removed by the amendments and respectfully request that the rejection

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<sup>1</sup> A number of interesting reviews exist that give an overview of the importance of osteoblast cells in therapeutic research, these include: Nuttall ME, Gimble JM. "Is there a therapeutic opportunity to either prevent or treat osteopenic disorders by inhibiting marrow adipogenesis?" Bone. 2000 Aug;27(2):177-84. Demers LM, Costa L, Lipton A. "Biochemical markers and skeletal metastases." Cancer. 2000 Jun 15;88(12 Suppl):2919-26. Review. Ghani AN. "Bone metabolism: newer perspectives." Malays J Pathol. 1997 Jun;19(1):17-9. Review.

be withdrawn.

On pages 6-7 of the office action, the examiner objects to the claiming of variant proteins having at least 90% amino acid identity to SEQ ID NO:1 (essentially claim 2) on written description grounds and quotes *Fires v. Revel* and *University of California v. Eli Lilly* to support this rejection. The Applicants fully acknowledge the case law and agree that an adequate written description requires more than "a mere statement that it is part of the invention and a reference to a potential method of isolating it..." but requires a description of the molecule (in this case a protein) itself. In the present case, the applicant claims variant proteins having at least 90% amino acid identity to SEQ ID NO:1. Given the current state of computing technology well known in the art, one of skill in the art would have little trouble in identifying such protein variants, or indeed in producing a list of all such possible proteins. The specification need not list every conceivable embodiment of the invention in order to produce an adequate written description sufficient to allow one to make and use such embodiments of the invention, thus, it is believed that the applicants have adequately fulfilled their burden under the written description requirements and respectfully request that the rejection be withdrawn.

**Claim Rejections Under 35 U.S.C. § 112, second paragraph**

Claims 36 and 37 have been rejected under 35 U.S.C. § 112 as a corollary to the 35 U.S.C. § 101 rejections. These claims have been canceled.

**Claim Rejections Under 35 U.S.C. § 102**

Claims 1, 2, 12, 21, 22 and 36-39 have been rejected under 35 U.S.C. § 102 as allegedly anticipated by Prywes because of the recitation of "comprising. . .a biologically active fragment..." This language has been removed by the present amendments, therefore the rejection is now moot.

**CONCLUSION**

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding rejections. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact Applicants' Attorney at (650)855-0555.

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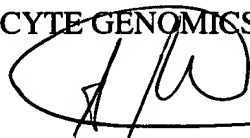
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Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 09-0108. This form is enclosed in duplicate.

Respectfully submitted,

INCYTE GENOMICS, INC.



Date: 8/15/00

Adam Warwick Bell, D.Phil.

Reg. No. 43,490

Direct Dial Telephone: (650) 621-7542

3160 Porter Drive  
Palo Alto, California 94304  
Phone: (650) 855-0555  
Fax: (650) 849-8886